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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,199	09/24/2001	Mitsuaki Yamamoto	213966US0PCT	6427

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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FOSTER, CHRISTINE E

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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06/13/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

**Application No.**

09/926,199

**Applicant(s)**

YAMAMOTO ET AL.

**Examiner**

Christine Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/16/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 62-88 is/are pending in the application.
- 4a) Of the above claim(s) 63-70 and 72-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 62 and 71 is/are rejected.
- 7) ☒ Claim(s) 62 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/18/05, 7/7/06.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/2006 has been entered.
2. Claims 31-61 were canceled by the amendment, and new claims 62-88 were added.

### *Election/Restrictions*

3. Newly submitted claims 63-70 and 72-88 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
4. Newly submitted claims 63-70 and 72-84 recite species of compounds that do not read on Applicant's elected species of **saponins**, or in particular **digitonin** (see the Office action mailed 2/7/06 at pages 3-4 and Applicant's reply of 2/13/06).
5. Newly submitted claims 75-87 recite methods of quantitating cholesterol; however, such methods do not read on the elected invention of a **reagent**. It has been established that the claims lack unity of invention (see the Office action mailed 6/17/05; Applicant's election in the reply of 7/18/05 at page 1; and the Office action mailed 2/7/2006 at page 2).
6. Newly submitted claim 88 recites a compound selected from the group consisting of **lectins**, which does not read on the elected species of **saponins**, or in particular **digitonin** (see the Office action mailed 2/7/06 at pages 3-4 and Applicant's reply of 2/13/06).

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 63-70 and 72-88 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 62-88 are pending in the application, with claims 63-70 and 72-88 currently withdrawn. Claims 62 and 71 are subject to examination below.

***Objections/Rejections Withdrawn***

7. The objection to the specification as containing new matter (see the previous Office action at page 3) is withdrawn in view of the replacement abstract filed 12/18/06.

8. The objections to and rejections of claims 31-32, 40, and 44-45 as set forth in the previous Office action have been withdrawn in view of the claims' cancellation.

***Information Disclosure Statement***

9. Applicant's Information Disclosure Statement filed 7/7/06 has been received and entered into the application. The references therein have been considered by the examiner as indicated on the attached form PTO-1449.

The entry listing related case 09/926,199 has been lined through because it refers to the instant application under examination.

10. The information disclosure statement filed 7/18/05 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent

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application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

*Specification*

11. The disclosure is objected to because of the following informalities:
12. The word "first" is misspelled on p. 17, line 23 (see the replacement paragraph on p. 4 of Applicant's response filed 12/5/05). See the Office action mailed 3/17/2006 at page 4 and the Office action mailed 8/9/2005 at pages 2 and 5.
13. The word "suzukacillin" is apparently misspelled at p. 8, line 23 and in the replacement abstract submitted on 12/18/06. See the Office action mailed 3/17/2006 at page 5.
14. The amendment of 12/18/06 (see page 2) includes the following instruction:  
Page 4, line 25, replace "" [sic] with --SUMMARY OF THE INVENTION--.  
Applicant's instructions are unclear. Specifically, is not clear what text should be replaced with the indicated header, since no text appears between the quotation marks above. Clarification is requested.

Appropriate correction is required.

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*Claim Objections*

15. Claim 62 is objected to because of the following informalities:

The word “suzucasylin” appears to be a typographical error that should read “suzukacillin”.

Clarification and/or appropriate correction is required.

*Claim Rejections - 35 USC § 112*

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claim 62 recites the surfactant “polyoxyethylene **higher alcohol** ether”, which is indefinite because it is unclear what compounds or structural groups are being invoked by reference to “higher alcohol”. The specification does not define this term, such that it is not clear what compounds would be considered to fall within this genus. Furthermore, the term “higher” is a relative term which thus renders the claim indefinite. The term “higher” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree in the context of “higher alcohol” ethers, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For all of these reasons, the metes and bounds of the claim are unclear.

*Claim Rejections - 35 USC § 102*

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claim 62 is rejected under 35 U.S.C. 102(b) as being anticipated by Hino et al. (US 5,773,304, Applicant's IDS of 3/4/05) in light of the evidence of Hirai et al. (US 4,940,660).

Hino et al. teach reagents to be employed for determination of cholesterol in HDL, in particular: (1) a substance that forms a complex with lipoproteins other than HDL (see especially column 2, lines 36-47), (2) a surfactant (see especially column 2, line 60 to column 3, line 51, and Example 1), and (3) the enzymatic reagents cholesterol esterase and cholesterol oxidase, or alternatively cholesterol esterase and cholesterol dehydrogenase (column 3, lines 33-39). The substance (1) reads on the instantly claimed **compound** since examples of such substances include **polyethylene** glycol (see column 2, lines 36-47), which is a species that anticipates the genus of "polyenes" as recited in claim 1. The substance (2) anticipates the claimed **surfactant** since exemplified surfactants include Triton X-100 (Example 1). Hirai et al. is cited as an evidentiary reference to show that Triton X-100 is a trademark corresponding to the surfactant polyoxyethylene (10) octylphenyl ether as recited in claim 1 (see column 6, lines 55-57).

21. Claims 62 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. ("Ultrastructural localization of cholesterol by enzyme histochemistry" Histochem J. 1981 Nov;13(6):1017-28) in light of the evidence of Hirai et al. (US 4,940,660).

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Jones et al. teach the following ingredients, which are used together in a method for localizing cholesterol: (1) digitonin (see in particular the abstract; page 1019, Table 1 and “Additional histochemical procedures”, page 1024, the first full paragraph of text; Figure 14; and pages 1026-1028, “Discussion”); (2) the surfactant Triton X-100, which is polyoxyethylene (10) octylphenyl ether in light of the evidence of Hirai et al. (see Hirai et al. at column 6, lines 55-57); see the abstract of Jones et al. and page 1018, “Incubation”); and (3) the enzymatic reagent that is cholesterol oxidase and cholesterol esterase (page 1018, “Incubation”). Jones et al. teach that the above ingredients are provided separately, where the sample is first incubated with cholesterol esterase and cholesterol oxidase (see page 1018, the first full paragraph and the section “Incubation”) followed by immersion in digitonin (page 1019); therefore, the reference anticipates the claimed invention.

### ***Double Patenting***

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.



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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 62 and 71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,939,682 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '682 patent claims a test piece comprising the instantly claimed compound, surfactant, and enzymatic reagent. In particular, the '682 patent claims an **enzymatic reagent** for measuring cholesterol, which may be cholesterol esterase and cholesterol oxidase or alternatively cholesterol esterase and cholesterol dehydrogenase (see especially claims 1 and 7-8). The test piece also includes two surfactants, the first of which may be polyoxyethylene alkylene phenyl ether or polyoxyethylene alkylene tribenzyl phenyl ether (see claim 5), which are two of the **surfactants** recited in instant claim 1. The second surfactant may be polyoxyethylene alkylether or other polyoxyethylene compounds (see claim 6); these **polyoxyethylenes** represent species that anticipate the claimed genus of **polyenes** as recited in instant claim 1.

24. Claims 62 and 71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/184,118. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '118 application claims a test piece comprising the instantly claimed compound, surfactant, and enzymatic reagent. In particular, the '118 application claims an **enzymatic reagent** for measuring cholesterol, which may be cholesterol esterase and cholesterol oxidase or alternatively cholesterol esterase and cholesterol dehydrogenase (see especially claims

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1 and 8-9). The test piece also includes two surfactants, the first of which may be polyoxyethylene alkylene phenyl ether or polyoxyethylene alkylene tribenzyl phenyl ether (see claim 6), which are two of the **surfactants** claimed in instant claim 1. The second surfactant may be polyoxyethylene alkylether or other polyoxyethylene compounds (see claim 7); these **polyoxyethylenes** represent species that anticipate the claimed genus of **polyenes** as recited in instant claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 62 and 71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 11/184,117. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '117 application claims a test piece comprising the instantly claimed compound, surfactant, and enzymatic reagent. In particular, the '117 application claims an **enzymatic reagent** for measuring cholesterol, which may be cholesterol esterase and cholesterol oxidase or alternatively cholesterol esterase and cholesterol dehydrogenase (see especially claims 1 and 8-9). The test piece also includes two surfactants, the first of which may be polyoxyethylene alkylene phenyl ether or polyoxyethylene alkylene tribenzyl phenyl ether (see claim 6), which are two of the **surfactants** claimed in instant claim 1. The second surfactant may be polyoxyethylene alkylether or other polyoxyethylene compounds (see claim 7); these **polyoxyethylenes** represent species that anticipate the claimed genus of **polyenes** as recited in instant claim 1.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

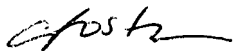
26. Applicant's arguments filed 12/18/2006 are acknowledged (see Reply, pages 9-11) but are moot in light of the new grounds of rejection set forth above.

***Conclusion***

27. Claims 62 and 71 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christine Foster, Ph.D.  
Patent Examiner  
Art Unit 1641



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